UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

WASHINGTON STATE PHARMACY ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, SHIRAZ SPECIALTY PHARMACY, CAMMACK'S PHARMACY, INC., RITZVILLE DRUG COMPANY, SOAS, LLC, CAMP RILEY DRUG COMPANY d/b/a PHARM-A-SAVE, and GENOA HEALTHCARE, LLC,

Plaintiffs,

vs.

CHRISTINE GREGOIRE, not individually, but Solely in her official capacity as Governor of the State of Washington, SUSAN N. DREYFUS, not individually, but solely in her official capacity as Interim Secretary of the Washington State Department of Social and Health Services, DOUG PORTER, not individually, but in his official capacity as Assistant Secretary of the Health and Recovery Services Administration, Washington State Department of Social and Health Services, THE WASHINGTON STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES, and HEALTH AND RECOVERY SERVICES ADMINISTRATION,

Defendants.

NO.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

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The Washington State Pharmacy Association ("WSPA"), the National Association of Chain Drug Stores ("NACDS"), the National Community Pharmacists Association ("NCPA"), Shiraz Specialty Pharmacy, Cammack's Pharmacy, Inc., Ritzville Drug Company, SOAS, LLC, Camp Riley Drug Company, and Genoa Healthcare, LLC ("Genoa") complain against Christine Gregoire, not individually, but solely in her capacity as Governor of the State of Washington, Susan N. Dreyfus, not individually, but solely in her capacity as the Secretary, Washington State Department of Social and Health Services, Doug Porter, not individually, but solely in his capacity as Assistant Secretary, Health and Recovery Services Administration, Washington State Department of Social and Health Services, the Washington State Department of Social and Health Service (the "Department"), and the Health and Recovery Services Administration for injunctive and declaratory relief.

This Complaint seeks to enjoin the Defendants from reducing by, on average, slightly more than four percent (4%) Medicaid reimbursement based on Average Wholesale Price ("AWP") for drug products paid to pharmacies for dispensing prescription drugs to Medicaid patients. The Court should grant injunctive relief because: (a) Section 1902(a)(30)(A) of the Social Security Act ("Section 30(A)") preempts these reimbursement cuts because the Department failed to properly consider and abide by the "quality of care" and "access" provisions of Section 30(A); (b) the Department violated federal and state law by failing to obtain approval from the United States Department of Health and Human Services' Centers for Medicare & Medicaid Services ("CMS") before implementing the cuts to reimbursement; (c) the Department violated state law by failing to consult with stakeholders and other interested parties regarding the reimbursement cuts; (d) the Department violated federal law by making reimbursement payments to pharmacies that are lower than the Department's own best estimates of pharmacies' actual acquisition costs; and (e) the reimbursement cuts will reduce the quality of care delivered to Medicaid beneficiaries in Washington and as such violates state law. Finally, a mere six months ago, this court enjoined similar cuts in

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reimbursement for the same reasons. For these reasons, which are more thoroughly set forth below, the Pharmacies are entitled to a declaratory judgment that the impending reimbursement cut violates federal and state law, and injunctive relief.

JURISDICTION AND VENUE

1. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1331. In addition, this Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

2. Venue is appropriate in this jurisdiction pursuant to 28 U.S.C. § 1391 because the persons sued in their official capacity all maintain offices within this District and the State entities are headquartered within, and a substantial part of the events giving rise to these claims occurred in, this District.

PARTIES

3. WSPA is a professional and trade association with over 1,700 members including pharmacies, pharmacists and technicians located throughout the state of Washington. Its main purpose is to promote the interests of providers of pharmaceutical services within Washington. WSPA also seeks to ensure that patients have access to safe and appropriate care, which includes lobbying and otherwise acting to promote reasonable reimbursement for pharmacy services. Many of the members of WSPA participate in Washington's Medicaid program.

4. NACDS is a national association whose members include 16 pharmacy chains in Washington with over 534 individual pharmacies in the state of Washington. NACDS's mission includes ensuring its members are adequately reimbursed by federal and state healthcare programs and ensuring patient access to pharmaceutical care. Members of NACDS participate in Washington's Medicaid program.

5. NCPA is a national association whose members include independent community pharmacies and pharmacists including independent community pharmacists in the

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state of Washington. The nation's independent community pharmacists are small business owners and multifaceted healthcare providers who represent a vital part of the United States' healthcare delivery system. NCPA's members are committed to high quality patient care and services and to restoring, maintaining, and promoting the health and well-being of the general public, including Medicaid patients. NCPA represents the professional and proprietary interests of independent community pharmacists, and promotes and defends those interests, including those interests pertaining to federal and state healthcare programs. Many of the members of NCPA participate in Washington's Medicaid program.

6. Genoa provides on-site pharmaceutical services for community mental health centers throughout the United States. Genoa operates eight in-house pharmacies in the State of Washington serving patients with severe mental health issues. Many of the patients Genoa serves at its Washington community mental health centers are Medicaid beneficiaries.

7. Shiraz Specialty Pharmacy is a pharmacy licensed in Washington located in Everett, Washington. Shiraz Specialty Pharmacy provides services to Medicaid beneficiaries including dispensing prescription drug products subject to the September 26, 2009 reimbursement cut.

8. Cammack's Pharmacy, Inc. d/b/a Jim's Pharmacy is a pharmacy licensed by Washington located in Port Angeles, Washington. Jim's Pharmacy provides services to Medicaid beneficiaries including dispensing prescription drug products subject to the September 26, 2009 reimbursement cut.

9. Ritzville Drug Company is a pharmacy licensed by Washington located in Ritzville, Washington. Ritzville Drug Company serves a rural community. It is the only pharmacy within fifty miles – approximately a one hour drive - of its location in any direction. Ritzville Drug Company provides services to Medicaid beneficiaries including dispensing prescription drug products subject to the September 26, 2009 reimbursement cut.

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10. SOAS, LLC operates three licensed pharmacies in the State of Washington: Island Drug (230 SE Pioneer Way, Oak Harbor, WA 98277), Island Drug (11042 SR 525 #130, Clinton, WA 98236), and La Conner Drug (708 E. Morris St., PO Box 477, LaConner, WA 98257). SOAS's three pharmacies provide services to Medicaid beneficiaries, including dispensing prescription drug products subject to the September 26, 2009 reimbursement cut.

11. Camp Riley Drug Company d/b/a Pharm-A-Save is a pharmacy licensed by the State of Washington located in Monroe, Washington. Pharm-A-Save provides services to Medicaid beneficiaries, including prescription drug products subject to the September 26, 2009 reimbursement cut.

12. Christine Gregoire is named solely in her official capacity as Governor of the State of Washington. As Governor, Ms. Gregoire has executive responsibility for the Department, the single state agency responsible for administering the Medicaid Program in Washington. RCW § 74.04.050.

13. Susan N. Dreyfus is sued solely in her capacity as Secretary of the Department.

14. Doug Porter is sued solely in his capacity as the Assistant Secretary of the Department's Health and Recovery Services Administration, the designated medical assistance unit for Medicaid-related activities within the Department.

15. The Department is sued in its capacity as the agency charged with administering the Medicaid program in Washington.

16. The Health and Recovery Services Administration is the entity within the Department that is responsible for administering the Medicaid program and implementing Medicaid reimbursement rates.

Laws Governing Washington's Medicaid Program.

17. Medicaid is a joint federal and state program created under Title XIX of the Social Security Act to provide health care to indigent and otherwise disadvantaged Americans. Federal and state government agencies share responsibility for funding the

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Medicaid program. Each state administers its Medicaid program in accordance with federal and state law, as well as a State-authored Medicaid State plan, which the state submits to CMS, and CMS reviews and approves.

18. The Washington Medicaid State Plan ("State Plan") is the Department's comprehensive written statement that describes the nature and scope of the State Medicaid program and gives assurances that the Department will administer the State Plan in conformity with the specific requirements of the Social Security Act. The State must amend its State Plan before implementing "material changes," including those made to "reflect . . . court decisions" in the First DataBank case. 42 U.S.C. § 1396, 42 C.F.R. § 430.12(c)(1)(i) and (ii).

19. Pursuant to the State Plan, Washington agreed to administer the state Medicaid program "in accordance with the provisions of this State plan, the requirements of titles XI and XIX of the Act, and all applicable Federal regulations and other issuances of the Department." Relevant sections to the Washington State Plan are attached as Exhibit A. *See* Washington State Plan, General Program Administration, page 1.

20. In order to comply with federal law, a state Medicaid program must comply with the "quality of care" clause of Section 30(A) which provides in pertinent part:

> (a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments are consistent with efficiency, economy, and quality of care . . . .

42 U.S.C. § 1396a(a)(30)(A).

21. A state Medicaid program must also comply with the "access" clause of Section 30(A) which provides in pertinent part:

> (a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments . .

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> . are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Id.

22. For that reason, federal regulations require the Department to offer payments to providers "sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204.

23. Therefore, to demonstrate that reimbursement complies with federal statutes, federal regulations, and the State Plan, and that its reimbursement is not arbitrary and capricious, a State must show that it has evaluated, prior to implementation of new rates and methodologies, that the reimbursement provided complies with the "quality of care" and "access" provisions of Section 30(A), and will ensure enough providers are enlisted so that services under the plan are available to recipients at least to the extent that they are available to the general public.

The Method Used to Calculate Washington's Medicaid Reimbursement.

24. Retail pharmacies that take part in the Medicaid program dispense prescription drugs and provide related services to patients who are covered by Medicaid. In return, those retail pharmacies apply for, and receive, reimbursement payments from the Department.

25. Reimbursement paid to Medicaid-enrolled pharmacies for drug products and services contains two components: (1) a reasonable dispensing fee meant to compensate a pharmacy for the dispensing costs that it incurs and the associated services that it provides, and (2) reimbursement for the drug product itself.[1]

[1] A reimbursement rate for each individual drug product is set for, and corresponds to, the National Drug Code ("NDC") for that drug product. A NDC is a unique numerical code that identifies the manufacturer, active ingredients, dosage size, and packaging for a drug product.

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26. With regard to the first component of reimbursement, Washington does not provide a reasonable dispensing fee that compensates pharmacies for the dispensing costs that they incur and the related services that they provide. In fact, Washington's fee is between $8.00 and $9.50 per prescription below pharmacies' actual costs of dispensing.

27. With regard to the second component of reimbursement, Washington's State Plan provides that reimbursement payments for prescription drug products cannot exceed the lowest of five amounts. One of the five possible payments amounts – and, in practice, the payment amount that is often used - is the "estimated acquisition cost (EAC)" of a prescription drug. *See* Washington State Plan, Attachment 4.19-B, p. 2.

The AWP Reductions

28. First DataBank, Inc., a clearinghouse of data pertaining to the pharmaceutical industry, publishes lists of prescription drugs and the AWP for each prescription drug. The Department uses First DataBank AWP data in calculating its EAC.

29. On March 17, 2009, First DataBank entered into a class action settlement agreement ("First DataBank Settlement") in which it agreed to reduce the mark-up to the wholesale average cost ("WAC") from 1.25 to 1.20 when setting AWPs for 1,442 NDCs. In addition, First DataBank announced it would voluntarily cut the WAC mark-up to 1.20 when setting AWPs for thousands of NDCs where the mark-up exceeded 1.20. In effect, First DataBank agreed to reduce its listed AWP for virtually all NDCs by, on average, 4%. These reductions of AWPs occurred on September 26, 2009.

30. The practical effect of First DataBank's reduction of the mark-up to WAC when setting AWPs is that the reimbursement for drug products tied to AWP that the Department pays has been reduced by slightly more than 4%.

31. As a result of the AWP reductions, reimbursement payments will be at virtually the same levels as reimbursement payments that this Court enjoined approximately six months ago, due to violations of the same laws discussed herein.

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The Department's Failure To Comply With Federal And State Laws

32. There is nothing in the administrative record that suggests that the Department considered or otherwise took into account either the "quality of care" or the "access" provisions of Section 30(A) prior to this reduction of reimbursement payments.

33. Indeed, the plaintiffs have not found any evidence that the Department took any steps to determine how the reimbursement reduction would affect compliance with the "quality of care" or "access" provisions of Section 30(A).

34. Washington also has not certified to the federal government in its State Plan that the reduced reimbursement as of the September 26, 2009 is "designed to enlist participation of a sufficient number of providers in the program so that eligible persons can receive the medical care and services included in the plan at least to the extent these are available to the general population." *See* Washington State Plan, Attachment 4.19-B, p.1.

35. The Department has not obtained CMS approval prior to the reimbursement cut, which constitutes a material change to the State's operation of the Medicaid program, in violation of federal law and the State Plan. 42 C.F.R. § 430.12(c); Washington State Plan, General Program Administration Numbered Pages, at 86, Section 7.1.

36. There is no evidence that the Department provided public notice and the opportunity for public comment prior to the 4% reduction in AWP-based reimbursement, as it is required to do by 42 C.F.R. § 447.205.

37. There is no evidence that the new, reduced reimbursement payments were "designed to enlist participation" of sufficient providers of Medicaid, as the Department warranted in the state plan. *See* Washington State Plan, Attachment 4.19-B, p.1.

38. The Department has not made, and cannot make, the required analysis or findings that the new reduced reimbursement payments properly reflects the EAC for prescription drugs in the State of Washington. As a result, the Department has not made

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assurances to CMS that the reimbursement that went into effect on September 26, 2009 represents its best estimate of EAC as required by federal law. 42 C.F.R. §447.518.

39. Finally, the Plaintiffs have not found any evidence that the Department complied with state law requirements that the Department consult with other agencies and only implement cost controls that do not reduce the quality of care. RCW § 70.14.050(1), (2)(f).

Harm To Pharmacies And Their Patients

40. Unless enjoined, the effect of the reimbursement reduction will be catastrophic for Medicaid beneficiaries across Washington, as well as health service providers like the Pharmacies. The 4% AWP cut will result in the reimbursement for many drugs at a level below the Pharmacies' break even cost.

41. The Pharmacies will be forced to take drastic steps if the reimbursement cut goes into effect, including ceasing to fill Medicaid prescriptions and dropping their enrollment in the Medicaid program.

42. Medicaid patients, such as those served by Genoa, Shiraz Specialty Pharmacy, Cammack's Pharmacy, Inc., Ritzville Drug Company, SOAS, LLC, and Camp Riley Drug Company may lose access to lifesaving medications.

43. In short, there is real and immediate risk of harm to both the pharmacies and to Medicaid beneficiaries if the reimbursement cut goes into effect.

COUNT I FOR AN INJUNCTION HALTING THE REIMBURSEMENT CUT

44. The Plaintiffs incorporate Paragraphs 1 – 43 as if set forth fully here.

45. Pursuant to Section 30(A), the Department had a duty to consider efficiency, economy, quality, and access when establishing reimbursement rates. It is the state's obligation to develop methods and procedures for assuring that it complies with Section 30(A). Here, the Department acted in violation of the Supremacy Clause of the United States Constitution because it has failed to consider or give sufficient weight to the impact of the

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budget cut on quality of care or access to care for Medicaid beneficiaries required by Section 30(A), including the relationship of reimbursement payments to provider costs. Additionally, there is no evidence that the Department has complied with the requirements of Section 30(A) prior to its intended implementation of the September 26, 2009 reimbursement cut. Finally, it is evident that the new rates will directly result in a failure of the State to comply with the requirements of Section 30(A) because reimbursement will not be sufficient to assure "quality of care" and access.

46. It is also clear that the State has not taken adequate steps to set payment rates at such a level as to ensure that sufficient providers remain in the program so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 4407.204.

47. There is absolutely no evidence that the State made any finding or determination that the four percent (4%) reduction in AWP-based reimbursement represents the EAC of pharmacies, which is the amount the Department is obligated to pay providers under Federal law. 42 C.F.R. § 447.518.

48. There is no evidence that the State complied with state law by cooperating with other agencies and only implementing cost controls "without reducing the quality of care." RCW 70.14.050(1), (2)(g).

49. Moreover, the reimbursement reduction violates the clear intent of the Washington State Legislature that reimbursement for drug products not drop below AWP minus 16% as calculated before First DataBank reduced AWPs across the board. Proposed 2009-2011 Biennial Operating Budget and 2009 2nd Supplemental pg. 136.

50. It is also clear that the Department has not taken adequate steps to set reimbursement payments at such a level as to ensure that sufficient numbers of pharmacies remain in the Medicaid program so that services under the State Plan are available to

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recipients at least to the extent that those services are available to the general population. 42 C.F.R. § 447.204; See Washington State Plan, Attachment 4.19(i).

51. In short, the Department acted arbitrarily and capriciously, unlawfully and in violation of the Supremacy Clause of the United States Constitution when it reduced reimbursement payments to pharmacies. Based on the foregoing, Plaintiffs are likely to succeed on the merits.

52. Irreparable harm will occur as a result of the reimbursement cut because pharmacies will be forced to reduce levels of service, deny prescriptions to new Medicaid beneficiaries, shut down, reduce service hours, and/or refuse to take any Medicaid beneficiaries. Plaintiffs have no administrative remedy, nor any plain, speedy, or adequate remedy except by this complaint for injunctive relief.

53. The balance of harms favors entering the injunction because the physical and emotional harm suffered by Medicaid beneficiaries deprived of needed access to quality pharmaceutical products if the cut goes into place, as well as the inevitable loss of employment if the pharmacies are forced to close or lay off workers, outweighs monetary loss to the State. Moreover, the State is receiving additional federal funding, the express purpose of which is to avoid this type of cut.

54. It is in the public interest that the court grant the injunction because it is always in the public interest that State governments comply with federal and state law. Moreover, it is in the public interest to assure that Pharmacies can continue to serve Medicaid beneficiaries.

WHEREFORE, the Plaintiffs respectfully request that this Court enter an injunction enjoining the September 26, 2009 reimbursement payment cut.

COUNT II FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.205

55. The Plaintiffs incorporate Paragraphs 1 – 54 as if set forth fully here.

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56. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement payment cut violates 42 C.F.R. § 447.205.

57. 42 C.F.R. § 447.205 requires the Department to provide public notice of any significant proposed change in its methods and standards for setting reimbursement payments for services and provide an opportunity for public comment.

58. The Department did not provide public notice of the September 26, 2009 reduction in reimbursement as required by 42 C.F.R. § 447.205.

WHEREFORE, the Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT III FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.204

59. The Plaintiffs incorporate Paragraphs 1 – 58 as if set forth fully here.

60. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates 42 C.F.R. § 447.204.

61. 42 C.F.R. § 447.204, and the Washington State Plan, require the Department to set reimbursement payments at such a level as to ensure that sufficient providers remain in the program so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204; See Washington State Plan, 4.19(i).

62. The reduction in reimbursement will reduce the number of pharmacies in Washington's Medicaid program so as to make Medicaid services less available to Medicaid beneficiaries than they are to the general population, in contravention of Federal Regulations and the State Plan. 42 C.F.R. § 447.204.

WHEREFORE, the Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

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COUNT IV FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.518.

63. Plaintiffs incorporate Paragraphs 1 – 62 as if set forth fully here.

64. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement payment cut violates 42 C.F.R. § 447.518.

65. 42 C.F.R. § 447.518 requires the Department to make assurances to CMS that its proposed payment methodology for prescription drugs reflect the EAC for the drugs. 42 C.F.R. § 447.518. These assurances are based on findings made by the State regarding the EAC for prescription drugs. The State is required to retain and make available to CMS "data, mathematical or statistical computations, comparisons and other pertinent records to support its findings and assurances." 42 C.F.R. § 447.518.

66. There is absolutely no evidence that the State made any finding or determination that the four percent (4%) reduction represents the EAC of providers, which is the amount they are obligated to pay providers under Federal law. 42 C.F.R. § 447.518. Nor is there any evidence the Department has made the required assurances to CMS.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT V FOR DECLARATORY THAT THE SEPTEMBER 26, 2009 REIMBURSEMENT CUTS VIOLATE THE CLEARLY EXPRESSED WILL OF THE WASHINGTON STATE LEGISLATURE

67. Plaintiffs incorporate paragraphs 1 to 66 as if set forth here.

68. In the 2009-2011 Biennial Operating Budget and 2009 2nd Supplement the Legislature stated that the Department "will evaluate the reimbursement amount based on Average Wholesale Price (AWP), but DSHS will not reduce reimbursement for single-source brand-name drugs beyond 16 percent less than AWP." *See* Direct link:

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http://leap.leg.wa.gov/leap/budget/detail/2009/ho0911agydetail_0424.pdf; Pages 132-139, number 19 – Emphasize Use of Generic Drugs

69. The Legislature made that statement at a time when AWP was, on average, calculated 4% higher.

70. The effect of the September 26, 2009 reduction of AWPs is to reduce reimbursement payments beyond 16 percent less than AWP as calculated at the time the Legislature made the statement quoted above. In other words, reimbursement for single-source brand-name drugs has been reduced approximately 4% below the amounts identified by the Legislature as the minimum acceptable amount of reimbursement.

WHEREFORE, the Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT VI FOR DECLARATORY JUDGMENT THAT THE SEPTEMBER 26, 2009 REIMBURSEMENT CUT VIOLATES RCW § 70.14.050

71. The Plaintiffs incorporate Paragraphs 1 – 70 as if set forth fully here.

72. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates RCW § 70.14.050.

73. RCW § 70.14.050 requires that the Department consult with other agencies regarding changes in reimbursement payments and only implement cost controls that do not reduce the quality of care. RCW § 70.14.050(1), (2)(f).

74. The Department failed to comply with RCW § 70.14.050 with respect to the September 26, 2009 reimbursement cut.

WHEREFORE, the Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

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COUNT VII FOR DECLARATORY JUDGMENT THAT THE SEPTEMBER 26, 2009 REIMBURSEMENT CUT VIOLATES FEDERAL AND STATE LAW

75. The Plaintiffs incorporate Paragraphs 1 – 74 as if fully set forth here.

76. An actual controversy exists between the parties concerning whether the de facto reimbursement cut that will result from the First DataBank Settlement violates federal and state law.

77. For the reasons set forth above, the reimbursement cut violates both federal and state law as being preempted by Section 30(A) of the Social Security Act, contrary to Federal Regulations, contrary to state regulations, and contrary to the Medicaid State Plan.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the reimbursement cut unlawful, and enter an injunction preventing defendants from implementing the unlawful reimbursement cuts.

DATED this 29th day of September, 2009.

BENNETT BIGELOW & LEEDOM, P.S.

By _____

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM

State/Territory: WASHINGTON

Citation

42 CFR
430.10

(Omitted
45 CFR
Part 201,
AT-70-141)

As a condition for receipt of Federal funds under title XIX of the Social Security Act, the

DEPARTMENT OF SOCIAL AND HEALTH SERVICES
(Single State Agency)

submits the following State plan for the medical assistance program, and hereby agrees to administer the program in accordance with the provisions of this State plan, the requirements of titles XI and XIX of the Act, and all applicable Federal regulations and other official issuances of the Department.

REVISION: HCFA-PM-91-4 (BPD)
August 1991

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM

State/Territory: WASHINGTON

SECTION 7 - GENERAL PROVISIONS

Citation		
	7.1	Plan Amendments
42 CFR 430.12(c)		The plan will be amended whenever necessary to reflect new or revised Federal statutes or regulations or material change in State law, organization, policy or State agency operation.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: WASHINGTON

POLICY AND METHODS USED IN ESTABLISHING PAYMENT RATES FOR EACH OF THE OTHER TYPES OF CARE OR SERVICE LISTED IN SECTION 1905 (A) OF THE ACT THAT IS INCLUDED IN THE PROGRAM UNDER THE PLAN.

A. General

A. The state agency, the Department of Social and Health Services (department), will take whatever measures are necessary to assure appropriate audit of records wherever reimbursement is based on costs of providing care or service, or fee plus cost of materials.

B. The department maintains data indicating the allowed charges for claims made by providers. Such data will be made available to the Secretary of Health and Human Services upon request.

C. Payment methods are identified in the various sections of Attachment 4.19-B, and are established and designed to enlist participation of a sufficient number of providers in the program so that eligible persons can receive the medical care and services included in the plan at least to the extent these are available to the general population. Payment for extraordinary items or services under exception to policy is based upon department approval and determination of medical necessity.

D. Participation in the program is limited to providers of services who accept, as payment in full, the amounts paid in accordance with the fee structure.

E. State payment will not exceed upper limits as described in regulations found in 42 CFR 447.300 through 447.371. Any increase in a payment structure that applies to individual practitioner services is documented in accordance with the requirements of 42.CFR 447.203.

F. Providers, including public and private practitioners, are paid the same rate for the same service, except when otherwise specified in the State Plan.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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IV. Pharmacy Services

A. General Information:

1. The department reimburses only for prescription drugs provided by manufacturers that have a signed drug rebate agreement with the Department of Health and Human Services (HHS).

   Prescriptions for drugs may be filled and refilled at the discretion of the prescriber. For those drugs specified by the department, prior approval is required.

2. Payment for drugs purchased in bulk by a public agency is made in accordance with governmental statutes and regulations governing such purchases.

3. Each Medical Assistance client is granted the freedom to choose his or her source of medications, except when the client is covered under a managed care plan that includes the drug benefit.

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B. Upper Limits for Multiple-Source Drugs:

1. The reimbursement amount for a multiple-source drug for which CMS has established a specific federal upper limit (FUL) will be adopted-except when the FUL is lower than the pharmacies' actual acquisition cost for products available in Washington state.

   Based on information provided by representative pharmacy providers, a maximum allowable cost (MAC) is chosen.

   The chosen MAC is the lowest amount sufficient to cover in-state pharmacies' actual acquisition cost. Payments for multiple-source drugs for which CMS has set upper limits do not exceed, in the aggregate, the prescribed upper limits plus reasonable dispensing fees.

2. The department may establish a MAC for other multiple-source drugs that are available from at least three manufacturers/labelers. The MAC established does not apply if the prescriber certifies that a specific brand is "medically necessary" for a particular client.

3. Automated maximum allowable cost (AMAC) pricing applies to multiple-source drugs which are not on CMS's federal upper limits (FUL) list or the department's MAC list but are produced by three or more manufacturers/labelers, at least one of which has signed a federal drug rebate agreement. AMAC reimbursement for all products within a generic code number sequence is at the estimated acquisition cost (EAC) of the third lowest priced product in that sequence, or the EAC of the lowest
   priced drug under a federal rebate agreement in that sequence, whichever is higher. AMAC is recalculated each time there is a pricing updates to any product in the sequence.

4. The department will determine EAC by periodically determining the pharmacies' average acquisition costs for a sample of drug codes. The average cost will be based on in-state wholesalers' published prices to subscribers, plus an average upcharge, if applicable.

   The department will pay the EAC for a multiple source product if the EAC is less than the MAC/AMAC established for that product.

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IV. Pharmacy Services (cont.)

C. Upper Limits for "Other" drugs:

1. An "other" drug is defined as a brand name (single source) drug, a multiple-source drug where significant clinical differences exist between the branded product and generic equivalents, or a drug with limited availability.

2. Payments for "other" drugs are based on Average Wholesale Price (AWP) less a specified percentage. AWP is determined using price information provided by the drug file contractor.

3. See Supplement A for current EAC percentages.

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IV. Pharmacy Services (cont.)

D. Dispensing Fee Determination:

1. The department sets pharmacy dispensing fees based on results of periodic surveys.

2. The current dispensing fee payment system is multi-tiered. The dispensing fee paid to a pharmacy depends upon that pharmacy's total annual prescription volume (both Medicaid and non-Medicaid), as reported to the department. The exception to this is the contracted mail-order delivery service for prescription drugs; the dispensing fee is agreed upon during the Request For Proposal (RFP) process.

3. Pharmacies providing unit dose delivery service are paid the department's highest allowable dispensing fee for unit dose prescriptions dispensed. All other prescriptions filled by these pharmacies are paid at the dispensing fee level applicable to their annual prescription volume. The exception to this is the contracted mail-order delivery service for prescription drugs; the dispensing fee is agreed upon during the Request For Proposal (RFP) process.

4. A dispensing fee is paid for each ingredient in a compound prescription.

5. See Supplement A for current dispensing fees.

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REIMBURSEMENT FOR PHARMACY SERVICES

- General Information
- Prescription drug reimbursement is based on (1) the standard 11-digit National Drug Code (NDC) (5-4-2 format), and (2) the quantity filled.
- Total reimbursement for a prescription drug does not exceed the lowest of:

(1) Estimated acquisition cost (EAC) plus a dispensing fee;
(2) Maximum allowable cost (MAC) plus a dispensing fee;
(3) Federal Upper Limit (FUL) plus a dispensing fee;
(4) Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340 B of the Public Health Services (PHS) Act and dispensed to medical assistance clients; or
(5) The provider's usual and customary charge to the non-Medicaid population.

II. Payment

Providers must bill only after providing a service to an eligible client. Delivery of a service or product does not guarantee payment. For example, no payment is made when:

- The request for payment is not presented within the 365 day billing limit.
- The service or product is not medically necessary or is not covered;
- The client has third party coverage and the third party pays as much as or more than, the state allows for the service or product; or
- The service or product is covered in the managed care capitation rate.

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REIMBURSEMENT FOR PHARMACY SERVICES (Cont.)

III. Estimated Acquisition Cost (EAC)

A. First DataBank derives the Average Wholesale Price (AWP) of each product based on information they receive directly from each manufacturer or labeler. The appropriate percentage of the AWP that represents the Estimated Acquisition Cost (EAC) is determined.

B. Currently applied EAC percentages, effective for dates of service on and after 8/1/02, are:

- AWP-14% for single source drugs;
- AWP-14% for multisource drugs with four or fewer manufacturers/labelers;
- AWP-50% for multisource drugs with five or more manufacturers/labelers and no MAC or FUL; and
- 100% of certified AWP for infusion, injectable, and inhalation drugs with certified AWPs.

C. For the contracted mail-order delivery service of prescription drugs, the contactor/pharmacy guarantees that the average annual multisource discount, in aggregate for all drugs dispensed, will be at least 60% of AWP. An annual reconciliation will be performed and the contractor will pay any shortfall on a dollar-for-dollar basis. Contracted mail order delivery service for prescription drugs started 2/1/03. The EAC percentages for the contractor/pharmacy are:

I. AWP-19% for single source drugs; and
II. AWP-15% for multisource drugs.

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REIMBURSEMENT FOR PHARMACY SERVICES (Cont.)

IV. Dispensing Fees

A. A three-tier dispensing fee structure is used, with an adjusted fee allowed for pharmacies that participate in the Modified Unit Dose and/or True Unit Dose programs. The exception to the tiered dispensing fee system is the contractor/pharmacy that contracts to provide mail-order delivery service for prescription drugs; the mail-order dispensing fee is determined as a result of the competitive procurement process.

B. Listed below are the dispensing fee allowances for each drug ingredient in compounded and non-compounded prescriptions for pharmacies, effective for dates of service on and after 7/1/02:

- High-volume pharmacies (over 35,000 Rxs/yr) $4.20/Rx
- Mid-volume pharmacies (15,001-35,000 Rxs/yr).....$4.51/Rx
- Low volume pharmacies (15,000 Rxs/yr and under) $5.20/Rx
- Unit Dose Systems $5.20/Rx

C. A provider's dispensing fee is determined by the volume of prescriptions the pharmacy fills for medical assistance clients and the general public, as indicated on the annual prescription count survey distributed to pharmacies. The exception to this is the contractor/pharmacy that contracts to provide mail-order delivery service for prescription drugs; the mail-order dispensing fee is determined as a result of the competitive procurement process.

Contracted mail order delivery service for prescription drugs started 2/1/03. The dispensing fee for the contractor/pharmacy is:

- Contracted mail-order delivery service dispensing fee.....3.25/Rx